

§ 426.515

(3) Submitting a brief or a written statement when the parties submit briefs.

(c) *Service by amicus curiae.* Serving copies of any briefs or written statements on all parties.

§ 426.515 CMS' role in making the NCD record available.

CMS will provide a copy of the NCD record (as described in § 426.518) to the Board and all parties to the NCD review within 30 days of the receipt of the Board's order.

§ 426.516 Role of Medicare Managed Care Organizations (MCOs) and State agencies in the NCD review process.

Medicare MCOs and Medicaid State agencies may participate in the NCD review process only if they meet the *amicus* participant criteria listed in § 426.510(f)(3) and § 426.513.

§ 426.517 CMS' statement regarding new evidence.

(a) CMS may review any new evidence that is submitted, regardless of whether the Board has stayed the proceedings, including but not limited to new evidence:

- (1) Submitted with the initial complaint;
- (2) Submitted with an amended complaint;
- (3) Produced during discovery;
- (4) Produced when the Board consults with scientific and clinical experts; and
- (5) Presented during any hearing.

(b) CMS may submit a statement regarding whether the new evidence is significant under § 426.340, by a deadline set by the Board.

§ 426.518 NCD record furnished to the aggrieved party.

(a) *Elements of the NCD record furnished to the aggrieved party.* Except as provided in paragraph (b) of this section, the NCD record consists of any document or material that CMS considered during the development of the NCD, including, but not limited to, the following:

- (1) The NCD being challenged.
- (2) Any medical evidence considered on or before the date the NCD was issued, including, but not limited to, the following:

42 CFR Ch. IV (10–1–06 Edition)

- (i) Scientific articles.
- (ii) Technology assessments.
- (iii) Clinical guidelines.
- (iv) Statements from clinical experts, medical textbooks, claims data, or other indication of medical standard of practice.
- (v) MCAC transcripts.

(3) Public comments received during the notice and comment period.

(4) Coverage decision memoranda.

(5) An index of documents considered that are excluded under paragraph (b) of this section.

(b) *Elements of the NCD record not furnished to the aggrieved party.* The NCD record furnished to the aggrieved party does not include the following:

- (1) Proprietary data or privileged information.
- (2) Any new evidence.

§ 426.519 NCD record furnished to the Board.

The NCD record furnished to the Board includes—

- (a) Documents included in § 426.518(a); and
- (b) Privileged information and proprietary data considered that must be filed with the Board under seal.

§ 426.520 Withdrawing an NCD under review or issuing a revised or reconsidered NCD.

(a) CMS may withdraw an NCD or NCD provision under review before the date the Board issues a decision regarding that NCD. Withdrawing an NCD or NCD provision under review has the same effect as a decision under § 426.560(b).

(b) CMS may revise an NCD under review to remove or amend the NCD provision listed in the complaint through the reconsideration process before the date the Board issues a decision regarding that NCD. Revising an NCD under review to remove the NCD provision in question has the same effect as a decision under § 426.560(b).

(c) CMS must notify the Board within 48 hours of—

- (1) Withdrawing an NCD or NCD provision that is under review; or
- (2) Issuing a revised or reconsidered version of the NCD that is under review.